



**NTP**  
National Toxicology Program

# **Proposed Approach for the CERHR Evaluation of Low-Level Lead**

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Meeting of the NTP Board of Scientific Counselors*





## Presentation Outline

- Charge
- Nomination and Background
- Scope of the Evaluation
- Proposed Approach
- Comments





## **Charge**

To review and comment on the proposed approach for the development of the NTP evaluation of low-level lead.

### **Review Comments:**

- 1. Comment on the approach for the evaluation of low-level lead including development of the draft NTP Monograph for Low-Level Lead, the proposed use of external scientists, and involvement by the public.**
- 2. Provide any other comments you feel CERHR staff should consider in developing this evaluation project.**



## **Nomination and Background**

- **Evaluation of health effects of lead at lower levels of exposure**
- **Nominated by Dr. Elizabeth Whelan (NIOSH)**
  - ❖ Occupational exposure limit allows blood lead levels of 40 µg/dL
  - ❖ Health effects are well established at blood lead levels  $\geq 10$  µg/dL
  - ❖ Some epidemiological evidence of effects below 10 µg/dL
  - ❖ Worker populations include women of childbearing age
- **The NTP Board of Scientific Counselors:**
  - ❖ Expressed unanimous support for a CERHR evaluation of reproductive and developmental effects of blood lead levels below 40 µg/dL at the December 6, 2007 meeting



## Scope of the Evaluation

- **Epidemiological data for health effects at blood lead levels  $< 10 \mu\text{g/dL}$** 
  - ❖ Health effects are well established at higher levels
  - ❖ CDC's definition of elevated blood lead level is  $\geq 10 \mu\text{g/dL}$  for all age groups
  - ❖ The focus on health effects  $< 10 \mu\text{g/dL}$  will provide a weight of the evidence evaluation where there is more uncertainty
- **Expanded scope beyond effects on reproduction and development**
  - ❖ Including cardiovascular and renal effects
  - ❖ Effects of exposure prenatally, during childhood, adolescence, or as adults





## **Scope of the Evaluation**

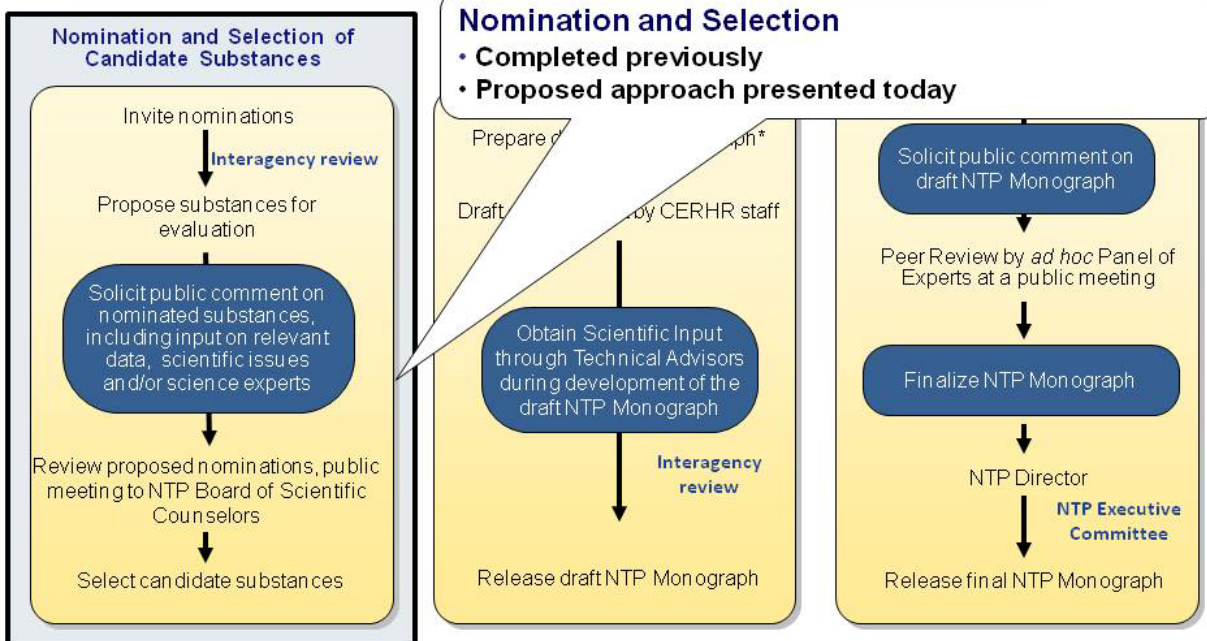
**The evaluation is designed to address the following questions:**

**What is the weight of evidence for adverse health effects associated with blood lead levels < 10 µg/dL?**

- ❖ What health effect(s) are associated with blood lead levels < 10 µg/dL?
- ❖ At which life stages (prenatal, childhood, adolescence, or adulthood) is the effect identified?
- ❖ What is the blood lead level associated with the health effect?
- ❖ Are there additional biomarkers of exposure associated with the effect (e.g., bone lead) and how does this biomarker relate to the blood lead level?



## CERHR Evaluation Process- Lead





## Proposed Approach: CERHR Evaluation Process- Lead

### Preparation of the Draft NTP Monograph

- Literature review
  - Epidemiological evidence
  - Supported by animal data
- WOE conclusions
  - Primarily based on epidemiological evidence
- Scientific input through
  - Public - FR notice
  - Technical advisors
  - Interagency review

Counselors

Select candidate substances

### Scientific Evaluation of Candidate Substances

Prepare draft NTP Monograph\*

Draft development by CERHR staff

Obtain Scientific Input through Technical Advisors during development of the draft NTP Monograph

Interagency review

Release draft NTP Monograph

### Peer Review and Release of NTP Monograph

Solicit public comment on draft NTP Monograph

Peer Review by *ad hoc* Panel of Experts at a public meeting

Finalize NTP Monograph

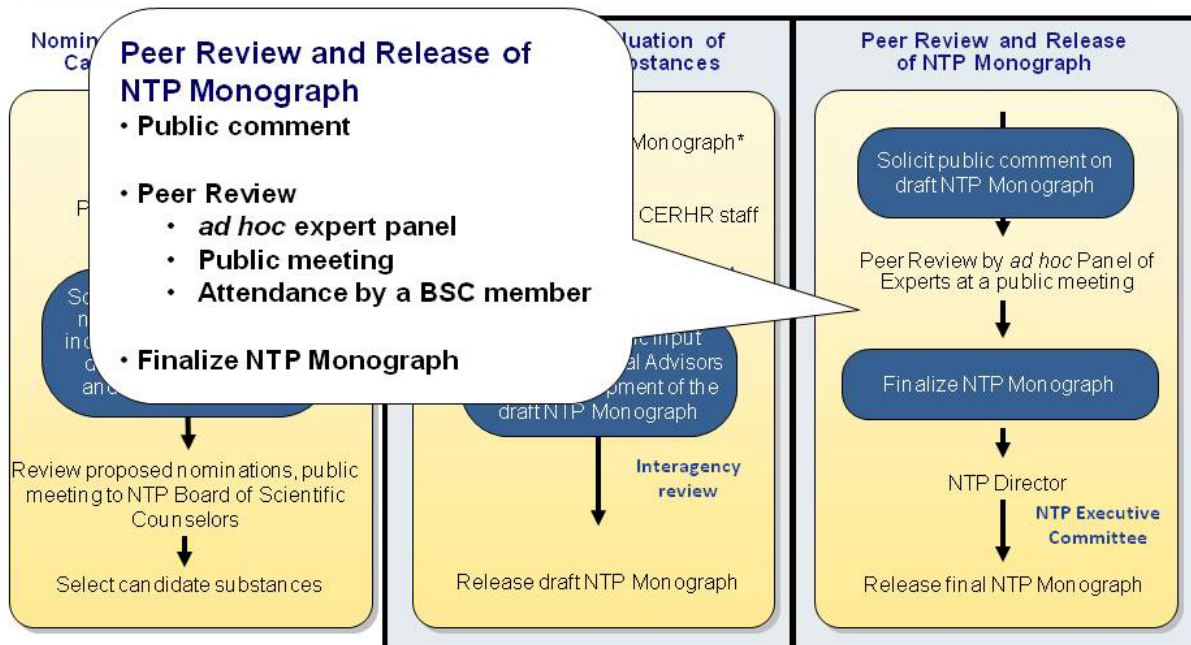
NTP Director

NTP Executive Committee

Release final NTP Monograph



## Proposed Approach: CERHR Evaluation Process- Lead





## **Significance and Expected Outcomes**

### **The NTP Monograph on Low-Level Lead will:**

- ❖ Provide an evaluation of the epidemiological data on health effects associated with blood lead levels < 10 µg/dL
- ❖ Provide clarity for health effects of lead at lower exposure levels
- ❖ Identify data gaps for evaluating the health effects associated with lead at blood lead levels < 10 µg/dL
- ❖ Develop research recommendations based on data gaps



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